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MECHANICAL TESTING OF A NEW PROSTHETIC ANTERIOR CRUCIATE LIGAMENT USING BIOCOMPATIBLE FIBROUS HYDROGEL CONSTRUCTS.

Jason S. Bach[1,2], Fabrice Detrez[3], Frances R. Baxter[1], Sabine Cantournet[3], Mohammed Cherkaoui[1,2], Laurent Corté[3], David N. Ku[1,2]

1- UMI 2958
Georgia Tech - CNRS
Metz, 57070
France

2- G.W. Woodruff School of Mechanical Engineering
Georgia Institute of Technology
Atlanta, GA 30332
USA

3- Centre des Matériaux (UMR 7633)
Mines ParisTech - CNRS
Evry, 91003
France

INTRODUCTION

The anterior cruciate ligament (ACL) is an important intra-articular structure in the knee joint that prevents excessive anterior tibial translation and resists internal rotational loads. Its rupture is one of the most common injuries of the knee and about 100,000 ACL reconstructions are performed each year in the United States. The current techniques for reconstruction involve replacing the ACL with autografts, most commonly from the hamstrings or patellar tendons, though use of these grafts is associated with various drawbacks, the most prominent of which is donor site morbidity. Over the past 30 years, numerous prosthetic devices for ACL replacement have been made with a wide range of materials. However none of them have demonstrated positive long term results *in vivo*, and no such devices are currently approved by the FDA for clinical use. Failures of previous devices mostly originate from a lack of biocompatibility due to immunogenic particulation or from mechanical failures causing prosthetic laxity and knee instability as the result of creep or rupture by wear and fatigue.

To circumvent these limitations, active research efforts are being carried out to develop tissue engineered ACL for which a biodegradable scaffold first replaces the ligament and is progressively replaced by a new reconstructed living tissue. While several systems have recently been designed and shown to give promising results, the control of the scaffold degradation and of the mechanical properties of the newly reconstructed tissue is one of the highly challenging issues that still need to be addressed before clinical use.

As an alternative to current graft reconstruction and future tissue engineered products, our group is currently exploring the potential of fibrous artificial ligaments made from poly(vinyl alcohol) (PVA) and ultrahigh molecular weight polyethylene (UHMWPE) for ACL replacement. Hydrogels of PVA have demonstrated very good biocompatibility and are currently being developed for a wide range of soft-tissue replacement applications including artificial meniscus and articular cartilage. Our central objective is to explore the potential of PVA based structures to meet the mechanical performance requirements of ACL replacement. To achieve this goal, our design criteria include 1) stiffness, 2) ultimate load/strength and 3) non-linear elasticity with toe region within the range of the normal ACL to a hamstring tendon. We hypothesize that braided and/or twisted textile structures of PVA hydrogel fibers, possibly reinforced with ultra-resistant UHMWPE fibers, can adequately meet these biomechanical requirements.

MATERIALS AND METHODS

Materials

Yarns composed of several twisted continuous fibers of PVA and UHMWPE. PVA fibers were chosen with a high dissolution temperature (>90°C) and formed a stable insoluble hydrogel at 40°C. NMR analysis showed that PVA is hydrolyzed over 95% and has a similar structure to biocompatible PVA grades used for cartilage replacement.

Sample preparation

PVA strands were prepared by winding PVA yarns and were in turn assembled into larger structures. Three types of samples were created for this study with various braiding patterns and PVA/UHMWPE compositions. Samples were approximately 10mm in diameter, which is approximately the same diameter as the native ligament and currently used grafts. Geometries and compositions are summarized in the chart below.

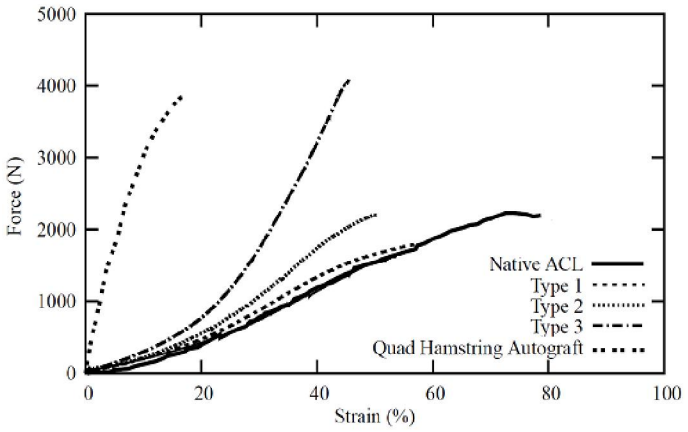
Sample	Components	Description
Type 1	16 PVA strands	4 twisted ropes each consisting of 4 PVA strands twisted together.
Type 2	22 PVA strands	Central core of 4 braided PVA strands surrounded by 6 twisted ropes each consisting of 3 PVA strands twisted together.
Type 3	21 PVA strands 27 UHMWPE yarns	Same as Type 2 but with 27 UHMWPE yarns together as a unit substituted for one of the PVA strands in the braided central core.

Mechanical testing

Hydrogel swelling was achieved by immersing samples in distilled water at 23°C for 24 hours prior to testing. Tensile testing was performed on an Instron 5966 apparatus using capstan fixations. Samples were tested less than 5 minutes after removal of water and pulled at a strain rate of about $10^{-2}s^{-1}$ ($1.5mm.s^{-1}$) which was fast enough to avoid any significant sample drying during testing. Instantaneous strain was measured by following ink marks with a video extensometer. Three samples were tested for each type.

RESULTS AND DISCUSSION

The tensile tests indicate that constructs made of PVA and UHMWPE, manufactured with appropriate dimensions for ACL replacement, can possess the fundamental mechanical properties required to restore ACL function. The load versus strain relationship for the average of each of the three sample types is shown below and compared to the tensile behavior of real ligaments and tendons [1-2].



All systems exhibited a non-linear elasticity with a toe region as well as an ultimate strain greater than 15% suitable for low tension and wear during the swing phase of walking. All three designs exhibited an acceptable value for linear stiffness within the range of the currently available ACL replacements. The Type 1 device had the approximate stiffness of the native ligament of a middle-aged person. The Type 2 device had a stiffness value very close to that of a young person's native ACL. Finally, the Type 3 samples had a stiffness approximately three times greater than the native ligament similar to autografts harvested from the patellar tendon or hamstrings.

The chart below compares these mechanical properties results derived from the graph above with the corresponding values for the device design inputs estimated from the literature.

Design Input	Required Value	Reference	Type 1	Type 2	Type 3
Stiffness	35-300N/%	[1-2]	40N/%	65N/%	150N/%
Ultimate Load	> 1750 N	[1-3]	1750N	2100N	4000N
Toe region strain	< 25%	[4]	~20%	~20%	~20%

Looking at the measured values for ultimate strength, a clear differentiation can be made among the three designs with the Type 3 device clearly exhibiting the greatest strength. The Type 1 PVA device had an ultimate strength of 1750N, which is near the lower bound of the normal range for the native ACL of a young person. The fact that patients rupture their original ACL indicates that forces have been generated *in vivo* which were greater than the ultimate strength of the native ligament and therefore a device with no safety factor may also fail. The Type 2 PVA device had an ultimate strength value approximately equal to average value for the young native ligament. The Type 3 device was shown to be the strongest, exhibiting an ultimate load approximately double the native ligament thereby providing a safety factor to ensure negligible failure risk.

CONCLUSION

The proposed fibrous structures based on PVA hydrogel meet the design criteria for an artificial anterior cruciate ligament with physiologic non-linear elasticity and adequate ultimate strength and strain. Overall, a device of PVA alone can provide excellent stiffness for ACL replacement with adequate strength comparable to that of the native ACL. Alternatively, reinforcement with a small quantity of UHMWPE also exhibits good elasticity with a 200% increase in strength that may provide more of a safety factor for synthetic ACL replacement devices.

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REFERENCES

1. Woo, S.L., et al., *Tensile properties of the human femur-anterior cruciate ligament-tibia complex. The effects of specimen age and orientation.* The American Journal of Sports Medicine, 1991. **19**(3): p. 217-225.
2. Kim, D.H., et al., *Twisting and Braiding Reduces the Tensile Strength and Stiffness of Human Hamstring Tendon Grafts Used for Anterior Cruciate Ligament Reconstruction.* Am J Sports Med, 2003. **31**: p. 861.
3. Brown, C.H. *Biomechanics of the semitendinosus and gracilus tendon grafts*. in *American Orthopaedic Society for Sports Medicine Conference*. 1995. Toronto, Canada.
4. Noyes, F.R. and E.S. Grood, *The strength of the anterior cruciate ligament in humans and Rhesus monkeys.* The Journal of Bone and Joint Surgery. American Volume, 1976. **58**(8): p. 1074-1082.